

Application No 10/628207 Application dated July 29,2003 Reply to office action of May 6, 2010

Your assessment is that it is a conceptual device (as per your e-mail of 26th may 2010).

Arguments'

Dear Dr Ho

I waited till today for your e-mail but it did not arrive, so I am sending the same contents as I sent in e-mail. I understand that my deadline runs out today.

I will like to inform you that it is not a conceptual device. Please note that USPTO fee etc is significant amount for me so I performed following exercise.

Took a PTCA guide wire.

Took a fine electrical insulation wire like structure simulating PTCA balloon shaft (one long one divided into two).

One part I further cut and stitched a spring with prolene at either end.

I used a PVC pipe to simulate the guiding catheter.

Then I asked another person to cover both pieces by cloth and keep changing their position so that it becomes double blind.

Then I asked 3 independent persons to observe the push (forward force) in both

They all observed that one with spring had more push.

Note it is during such pushing systems I observed following problems

- (A) If in monorail type balloon (rapid exchange) system if wire is out prior to spring then sometimes spring tends to buckle in guide cath and thus I wrote in specification that spring will be in part of balloon with guide wire.
- (B) Wire sometimes comes out through spring thus I wrote about guide wire receptacle in original application, (though I feel not required as when I loaded guide wire in spring compressed position the problem was automatically solved).
- (C) If spring came out from guiding cath before crossing the lesion, it tended to angulate and thus may cause dissection/endothelial injury in normal segment prior to obstructive lesion thus I wrote in application that it will be supplied in 2 lengths.
- (D) Long nose made use of device easier thus I wrote about longer nose.

Above is a cheap prototype to make sure that the concept will work.

Above four observations, mentioned in application, were after above prototype use.

It was done before applying and investing in application as application fee etc is significant amount for me.

If would have been extremely grateful if you had written same sentences(as in your e-mail) in your earlier objections then I could have shown you this prototype when I came to attend the TCT meet and met you.

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I can show you this prototype whenever I travel to US to attend any meeting next. Only when I get a patent I can think of investing through some partner for industrial production and clinical trials.

Thus I reinforce that this concept was tried on above prototype prior to application.

I will also like to inform you again that my application also has a well defined stent with well defined 3 drugs with defined release pattern.

I have given adequate replies to previous USPTO letters.

Conclusion

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted

Dr. Vipul Narain Roy)

5th June 2010